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EXAMINER

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1651

DATE MAILED: 12/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/505,285 | Applicant(s) BRETON ET AL. | |
| | Examiner Lora E. Barnhart | Art Unit 1651 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>8/19/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment received 10/17/05 canceling claims 1-8 and 10-29 and amending claim 9 is noted. Claim 9 is pending.

Election/Restrictions

Applicant's comments regarding the restriction requirement and the requirement for election of species are noted. The examiner wishes to point out for the record that an election of species requirement is for search purposes only and does not necessarily narrow the scope of patentable claims, since all nonelected disclosed species are rejoined at the time of allowance. See 37 C.F.R. §1.146 and M.P.E.P. § 809.02(c) for a discussion of species election practice. In short, electing one species does not preclude consideration of the nonelected species later in the prosecution, *i.e.* at the time of allowance. The fact that all of the original claims were generic was the precise reason for the requirement for species election; in the interest of expedient processing of applications, the examiner concentrates on the patentability of the entire invention as it pertains to one species. Once the invention *per se* is claimed in an allowable manner, all disclosed species are rejoined to the claims.

Since applicant has canceled all claims except for claim 9, there is no particular action to be taken by the examiner. Applicant's arguments are moot. The requirement is still deemed proper and is therefore made FINAL. Examination will commence on claim 9 ONLY.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recites "a photoprotecting effective amount", which is confusing. It is not clear whether the pet or the food is to be photoprotected. It is also not clear whether this phrase refers to an amount that is effective for photoprotection or to some other measurement. In addition, it is not clear whether the amount is meant to be protective against all intensities of all wavelengths of light, and in what manner the protection is enacted (e.g., protection of DNA from mutations; protection of skin from sunburn; prevention of freckles; or some other protection). Clarification is required. In the interest of compact prosecution, "photoprotecting effective amount" has been interpreted as "amount effective to protect a pet from at least one wavelength of light to some extent under some conditions."

In addition, it is not clear which components are required to be present in a photoprotecting effective amount. Applicant should amend the claim to clarify whether the probiotic lactic acid bacterium only, or the bacterium, yeast, and carotenoid, must all be present in a photoprotecting effective amount. Clarification is required.

Finally, the phrase "yeast and carotenoid **and derivatives thereof**" is not particularly defined in the specification. It is not clear whether the phrase "and derivatives thereof" refers to the carotenoid and the yeast, or just to the carotenoid. It is noted that at page 5, line 31, through page 6, line 6, applicant provides some examples

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of carotenoid derivatives and points out some functions and sources of said derivatives, it is not clear which compounds are encompassed by this phrase and which are excluded thereby. The specification provides no definition for a yeast derivative.

Clarification is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 9 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 and 25-30 of copending, currently commonly owned Application No. 10/505,305, which shares two inventors with the instant application. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the instant application is completely encompassed by the scope of the claims in the '305 application.

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Instant claim 9 is drawn to a composition comprising a photoprotecting effective amount of at least one probiotic lactic acid bacterium, and yeast and carotenoid or derivatives thereof. Claim 1 of the '305 application is drawn to a composition comprising a photoprotecting effective amount of at least one probiotic lactic acid bacterium, and at least one carotenoid or derivative thereof. Because claim 1 of the '305 application uses open-claim language ("comprising"), this claim fully encompasses claims to compositions comprising the two components of the '305 claim plus any other additional component. The generic nature of claim 9, which does not place any restrictions on the type or number of probiotic bacteria or carotenoids, or the physical form of the food composition, encompasses the specific claims of the '305 application (2-10, 25-30).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 9 is also provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 and 22-32 of copending, currently commonly owned Application No. 10/504,906, which shares two inventors with the instant application. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the instant application is completely encompassed by the scope of the claims in the '906 application.

Instant claim 9 is drawn to a composition comprising a photoprotecting effective amount of at least one probiotic lactic acid bacterium, and yeast and carotenoid or derivatives thereof. Claim 1 of the '906 application is drawn to a composition comprising a photoprotecting effective amount of at least one probiotic lactic acid bacterium, and at

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least one yeast. Because claim 1 of the '906 application uses open-claim language ("comprising"), this claim fully encompasses claims to compositions comprising the two components of the '906 claim plus any other additional component. The generic nature of claim 9, which does not place any restrictions on the type or number of probiotic bacteria or yeasts, or the physical form of the food composition, encompasses the specific claims of the '906 application (2-10, 25-30).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Shields, Jr. et al. (2000, U.S. Patent 6,156,355; reference A). The claim is drawn to a food composition comprising a photoprotecting effective amount of at least one probiotic lactic acid bacterium, and yeast and carotenoid or derivatives thereof, included in an ingestible carrier.

Shields, Jr. et al. teach dog food formulations comprising dried yeast, vitamin A beta carotene, probiotic bacteria (*Lactobacillus acidophilus* and *Enterococcus faecium*), and fermentation extracts of probiotic bacteria (*Bacillus subtilis*, *Aspergillus oryzae*, and

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Aspergillus niger), as well as numerous sources of protein, fat, and fiber (Examples 5 and 6; note in particular column 21, lines 48-49; 50-51; 54; and 60-63).

Shields, Jr. et al. do not specifically address the photoprotective properties of their food composition. Since the composition of Shields, Jr. et al. and the instantly claimed composition are substantially identical in composition, they inherently possess the same properties. M.P.E.P. § 2112 recites, "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). As discussed above, applicants do not particularly define the term "photoprotecting effective amount" within the specification, so the composition of Shields, Jr. et al. reads on the instant claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shields, Jr. et al. (reference A). The claim is drawn to a food composition as described above.

As discussed above, Shields, Jr. et al. teach dog food compositions comprising probiotic bacteria, yeast, and carotenoids. Shields, Jr. et al. do not explicitly teach photoprotecting effective amounts of probiotic bacteria or particular amounts of yeast or carotenoids.

The selection of the amount of probiotic bacteria, yeast, and carotenoids to be included in the composition of Shields, Jr. et al. would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that the amounts of these components may vary depending on the animal's dietary needs. Shields, Jr. et al. teach that the nutritional needs of dogs, for example, vary by breed type (column 4, line 63, through column 5, line 33). A holding of obviousness over the cited claims is therefore clearly required.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Claim 9 is also rejected under 35 U.S.C. 103(a) as being obvious over Baur et al. (2002, WO 02/28402; reference N) taken in view of Shields, Jr. et al. (reference A). The claim is drawn to a food composition as described above.

The applied reference has a common assignee and one common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Baur et al. teach that oral administration of 10^9 cfu/mL live or inactivated *Lactobacillus johnsonii* (La1) or *Lactobacillus paracasei* (ST11) to mice has a photoprotective effect in the context of ultraviolet-induced sensitivity to topical dinitrofluorobenzene (DNFB) application (Example 2). Baur et al. do not teach a

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composition comprising a photoprotecting effective amount of a probiotic lactic acid bacterium as well as yeast and carotenoids.

As discussed above, Shields, Jr. et al. teach dog food compositions comprising probiotic bacteria, yeast, and carotenoids.

A person of ordinary skill in the art would have had a reasonable expectation of success in coadministering the yeast and carotenoids of Shields, Jr. et al. with the photoprotecting probiotic bacteria of Baur et al. because Shields, Jr. et al. teach that compositions comprising all three components are suitable for ingestion by animals. The skilled artisan would have been motivated to combine the compositions of Baur et al. and Shields, Jr. et al. for the expected benefit that the photoprotecting effects of the Baur et al. bacteria could be achieved by feeding the animals a balanced diet formulation.

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to combine the compositions of Baur et al. and Shields, Jr. et al. because Baur et al. teach that the photoprotecting La1 and ST11 may be included in yogurt and other fermented food products that provide complete nutrition, and because Shields, Jr. et al. teach combining probiotic bacteria, yeast, and carotenoids in a pet food composition.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

No claims are allowed. No claims are free of the art.

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Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Friday, 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lora E Barnhart

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SANDRA E. SAUCIER
PRIMARY EXAMINER